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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,806	06/28/2001	Alan L. Greener	25436/1712	4116

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EXAMINER
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MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/894,806

Applicant(s)

GREENER ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-62 and 64-77 is/are allowed.
- 6) ☒ Claim(s) 1,22,28,63,81 and 82 is/are rejected.
- 7) ☒ Claim(s) 2-21,23-27,29-46 and 78-80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This office action is in response to an amendment filed 2/12/03. Claims 81 and 82 have been added and claims 1, 22, 23 and 57 have been amended. No new matter has been added by this amendment. Claims 1-82 are pending in this application.

#### ***Response to Amendment***

Claim objection to claim 57 as being duplicates of one another is withdrawn in light of amendment to claim 57.

Claim rejection of claim 23 under 35 U.S.C. 112, second paragraph, is withdrawn in light of amendment to claim 23.

Claim rejections under 35 U.S.C. 102 (b) as being anticipated by Bronshtein et al. WO 99/27071 (June 3, 1999) are withdrawn in light of arguments from applicant. Specifically in the declaration of Dr. Greener, paper number 10, it is explained that the XL-10<sup>TM</sup> competent cells of Stratagene that are used in the method of Bronhstein et al. for the preservation of sensitive biological samples by vitrification are not competent following the procedures by which the cells are dried.

Claim rejections under 35 U.S.C. 102(e) as being anticipated by Barnea et al. US application 2002/0081565 have been withdrawn in light of amendment to claim 1. Specifically, the claim has been amended to read that the cells are stored in the liquid

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state immediately prior to drying. Barnea et al. teach a method for generating storage-stable competent cells in which the cells are snap frozen then lyophilized.

Claim rejections under 35 USC 103 as being unpatentable over Jessee et al. WO 98/35018 are withdrawn in light of amendment to claim 1. Specifically, the claim has been amended to read that the cells are stored in the liquid state immediately prior to drying. Jessee et al. teach a method of freeze drying the competent cells in which cells are frozen at subzero temperatures under high vacuum prior to drying.

Claim rejections under 35 U.S.C. 103(a) as being unpatentable over Jessee et al. WO 98/35018 in view of Bronshtein et al. WO 99/27071 are withdrawn in light of the arguments from applicant presented above.

### ***Information Disclosure Statement***

The document listed on the IDS submitted 11/12/02, paper # 9 is an International Search Report. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each U.S. and foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications,

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applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609 subsection III. A(1) states, "the list ... must be submitted on a separate paper." Therefore, the document cited as the International Search Report has not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 subsection III. C(1).

### *Specification*

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code page 11 contains an embedded hyperlink. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites.

### *Claim Objections*

Claim 82 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 81 recites that "said cells are not frozen immediately prior to said drying" which is not further limited by claim 82, which recites "said cells are not frozen at least one minute prior to said drying". We are taught

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in the specification that the “cells are not frozen for at least one minute prior to said drying” (page 13, line 15-18). As this serves to define what is immediately prior to drying, claim 82 does not further limit claim 81.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 22, 28, 63, 81 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 81 are indefinite for reciting that “said cells are suspended in the liquid state immediately prior to said drying” and “said cells are not frozen prior to said drying”. These terms are not defined by the claims or the specification other than the disclosure that the “cells are not frozen for at least one minute prior to said drying” (page 13, line 15-18). The cells then appear to require at least one minute of remaining in a liquid state, unfrozen prior to drying. Without this as guidance, the claim is indefinite and the metes and bounds of the claim cannot be established. It would be remedial to amend 1 to read “said cells are suspended in the liquid state at least one minute prior to drying” and claim 81 to read “said cells are not frozen at least one minute prior to drying”

Claim 22 recites the limitation "said glass-forming matrix material" in claim 20. There is insufficient antecedent basis for this limitation in the claim. Applicants states in

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the amendment that claim 22 depends from claim 21 and therefore does have antecedent basis, the claim as written recites that claim 22 depends from claim 20.

Claims 28 and 63 contain the trademark/trade name FICOLL<sup>TM</sup>. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the manner in which the trademark appears in a patent is guided by the MPEP § 608.01(v). Specifically, trademarks used in patents or patent applications should be entirely capitalized.

### *Response to Arguments*

Applicant traverses the rejection of claims 28 and 63 under 112, second paragraph on pages 3-4 of the amendment filed 2/12/03, paper number 12A. Applicant argues that the use of the term ficoll is definite as ficoll has a CAS registry number and is referred to in 80 issued patents. In order to respect the proprietary nature of all trademarks and to make every effort to prevent their use in any manner that might adversely affect their validity, the trademarked term should be capitalized.

A Declaration under 37 C.R.F.R. 1.131 was filed 2/12/03, paper # 10, and signed by Dr. Alan Greener and Dr. James Jolly. Applicants provide statements that the instantly claimed invention was conceived of and reduced to practice prior to the October 30, 2000 priority date of the invention of Barnea et al. The instantly claimed invention has a priority date of 12/15/2000. In the attached Exhibit (exhibit 1), there are provided three notebook entries labeled A, B and C. Entry A and B from the notebook of Dr. Jolly details a protocol for drying cells in trehalose at 4°C to 30°C. These cells are analyzed for competence. Entry C details another drying protocol from the notebook of Latha

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Sundar in which the cells are dried in trehalose at 30°C. Of the three exhibits, exhibit C contains a date of 10/2/2000 in the margin. Applicant argues that they had therefore conceived of and reduced to practice, prior to October 30, 2000, a protocol in which competent cells are not freeze dried but are dried above freezing.

The Declaration filed on 2/12/03 under 37 CFR 1.131 is sufficient to overcome the Barnea et al. reference.

In the Declaration under 37 C.F.R. 1.132 was filed 2/12/03, paper # 10, Dr. Alan Greener traverses the rejection of claims under 102 as anticipated by Bronshtein et al. Specifically, applicant argues that the reference is not enabled as the cells that are dried in Bronshtein et al. are not competent prior to or after the drying period following the process of outgrowth and drying in the preservation solution.

The Declaration under 37 CFR 1.132 filed 2/12/03 is sufficient to overcome the rejection of claims under 35 U.S.C. 102 (b) as being anticipated by Bronshtein et al. WO 99/27071 (June 3, 1999). The vitrification procedure is used for drying biological materials but the disclosure does not teach that the cells are competent following the drying procedure provided in the disclosure.

Claims 2-21, 23-27, 29-46 and 78-80 are objected to as being dependent on a rejected claim but would be allowable if rewritten in an independent format reciting each of the limitations of the claims upon which they are currently dependent. Claims 47-62 and 64-77 are allowed. Claims 1, 22, 28, 63, 81 and 82 are rejected



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*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3291.

Maria B Marvich, PhD  
Examiner  
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May 3, 2003



**JAMES KETTER**  
**PRIMARY EXAMINER**